NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: CERTAIN CONSOLDATED ROFLUMILAST CASES	Civ. Action No.: 15-3375 (FLW) (DEA) **OPINION**

In this claim construction Opinion, the Court construes a single term, "roflumilast," in three patents held by Plaintiff AstraZeneca AB. These patents are related to Daliresp, a drug used to treat chronic obstructive pulmonary disease ("COPD"). After reviewing the parties' briefs and holding a *Markman* hearing, the Court ruled at the hearing that the term "roflumilast" as it appears in the patents at issue means "N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxybenzamide." This Opinion supplements the Court's oral decision at the *Markman* hearing.

I. Background

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and AstraZeneca AB ("Plaintiffs"), bring this Hatch-Waxman patent infringement suit against the following defendant generic drug manufacturers who have each submitted Abbreviated New Drug Applications seeking to market generic versions of Plaintiffs' product, Daliresp: Torrent Pharma Inc., Torrent Pharmaceuticals Ltd., Micro Labs USA, Inc., Micro Labs Ltd., Zydus Pharmaceuticals (USA), Inc., Strides Pharma, Inc., Strides Pharma Global PTE Limited, Apotex Corp., Apotex Inc., Prinston Pharmaceutical, Inc., Breckenridge Pharmaceutical, Inc., Citron

Pharma, LLC, MSN Laboratories Private Limited, Mylan Pharmaceuticals Inc., Hetero USA, Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited (collectively, "Defendants"). The active pharmaceutical ingredient in Daliresp is a chemical compound known as roflumilast. Plaintiff AstraZeneca AB is the current owner of five US patents that purportedly protect against the manufacture and use of roflumilast. Plaintiffs AstraZeneca UK Limited and AstraZeneca Pharmaceuticals LP market and distribute Daliresp in the United States.

On April 11, 2016, the parties submitted a joint claim construction and prehearing statement, which established that the sole claim term in dispute in this action is "roflumilast," which appears in three of the patents involved in this action: U.S. Patent Nos. 8,536,206 (the "'206 Patent"), 8,604,064 (the "'064 Patent"), and 8,618,142 (the "'142 Patent") (collectively, the "Patents-at-Issue"). The Patents-at-Issue are members of the same family of patents as U.S. Patent No. 7,470,791 (the "'791 Patent"), which purportedly protects novel processes for the production of highly pure roflumilast. '206 Patent at 1:1-17; '064 Patent at 1:1-19; '142 Patent at 1:1-19; '791 Patent at 8:29-20:6. Both the '206 Patent and the '064 Patent are process patents that claim methods for the treatment of an acute or chronic airway disorder using highly pure roflumilast. '206 Patent at 8:21-10:34; '064 Patent at 8:37-10:33. The '142 Patent claims a chemical composition composed primarily of roflumilast. '142 Patent at 8:22-9:21.

Roflumilast is the international nonproprietary name ("INN") for the chemical compound N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxybenzamide (the "Roflumilast Compound"). Each of the Patents-at-Issue identify the Roflumilast Compound as "INN: roflumilast." '206 Patent at 1:14-17; '064 Patent at 1:16-19; '142 Patent at 1:16-19. However, the parties disagree as to whether the Roflumilast Compound alone is the plain and ordinary meaning of "roflumilast" as it would have been understood by one of ordinary skill in the

art at the time of the alleged invention.[1] Plaintiffs assert that the plain and ordinary meaning of roflumilast is the Roflumilast Compound plus "active pharmaceutical ingredient." While Defendants assert that the Roflumilast Compound alone is the plain and ordinary meaning of roflumilast.

In addition, the parties disagree as to whether, under the circumstances here, roflumilast should be construed by its plain and ordinary meaning. Plaintiffs argue that the Court should construe roflumilast by the plain and ordinary meaning forwarded by Plaintiffs. However, Defendants argue that express disavowals in the specifications of the Patents-at-Issue and disclaimers that were made during the patent prosecution history require that roflumilast be construed more narrowly than its plain and ordinary meaning. Specifically, Defendants Torrent Pharmaceuticals Ltd., Torrent Pharma Inc., Breckenridge Pharmaceutical, Inc., Strides Pharma, Inc., Strides Pharma Global PTE Ltd., Prinston Pharmaceutical Inc., Mylan Pharmaceuticals, Inc., Citron Pharma LLC and MSN Laboratories Private Ltd. (collectively, "Torrent Defendants") contend that roflumilast should be construed as a product of the processes to produce roflumilast disclosed in the specifications of the Patents-at-Issue. In addition, Defendants Apotex Inc. and Apotex Corp., Micro Labs USA, Inc. and Micro Labs Ltd., Hetero USA Inc., Hetero Labs Limited Unit III, and Hetero Labs Limited, and Zydus Pharmaceuticals (USA) Inc. (collectively, the "Apotex Defendants") join Torrent Defendants in this construction, although originally they

[1] The parties do not dispute that a person of ordinary skill in the art as of March 2003, the priority date of the '206 Patent, '064 Patent and '142 Patent, would have an advanced degree in chemistry or a related discipline, along with several years of experience in pharmaceutical development or knowledge and experience, and/or access to others with knowledge and experience, in assessing the toxicology, pharmacology, and clinical utility of compounds useful to treat airway disorders.

asserted that roflumilast needs no construction, and should simply be given its plain and ordinary meaning. The below chart sets forth the parties' proposed constructions:

Disputed Claim	Torrent Defendants' Construction	Apotex Defendants' Original Construction	Plaintiffs' Construction
"roflumilast"	"N-(3,5-dichloropyridin-4-yl)-3-(cyclopropyl-methoxy)-4-(difluoro-methoxy)benzamide synthesized using a molar ratio of the anion of 4-amino-3,5-dichloropyridine to the activated derivative of 3-cyclopropylmethoxy-4-difluoromethoxybenzoic acid of at least 1.5 and at most 3"	Plain and ordinary meaning	"N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxy benzamide active pharmaceutical ingredient"

After a full briefing of the issue, on July 12, 2016, the Court held a *Markman* hearing at which the parties made oral argument. For the reasons set forth by the Court at the hearing, and as further supplemented by this Opinion, the Court construes "roflumilast" as it appears in the Patents-at-Issue by its plain and ordinary meaning – the chemical compound to which its INN corresponds.

II. Standard of Review

i. Claim Construction in General

Claims define the scope of the inventor's right to exclude. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). Claim construction determines the correct claim scope, and is a determination exclusively for the court as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978-79 (Fed. Cir. 1995) (*en banc*). Indeed, the court can only interpret claims, and "can neither broaden nor narrow claims to give the patentee something different than what it has

set forth" in the specification. *E.I. Du Pont de Nemours v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir.1988).

This interpretive analysis begins with the language of the claims, which is to be read and understood as it would be by a person of ordinary skill in the art. *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1372 (Fed. Cir. 2001); *see also Markman*, 52 F.3d at 986 ("The focus [in construing disputed terms in claim language] is on the objective test of what one of ordinary skill in the art at the time of invention would have understood the terms to mean"); *Phillips*, 415 F.3d at 1312-13. In construing the claims, the court may examine both intrinsic evidence (e.g., the patent, its claims, the specification, and prosecution history) and extrinsic evidence (e.g., expert reports, testimony, and anything else). *Pitney Bowes, Inc. v. Hewlett–Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999).

It is well settled that courts first look to intrinsic evidence when interpreting disputed terms. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed .Cir. 1996). Generally, words in patent claims are given their "ordinary and accustomed meaning as understood by one of ordinary skill in the art" at the priority date of the patent application. *Dow Chem.*, 257 F.3d at 1372; *K–2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1362 (Fed. Cir. 1999). The claims must be construed objectively in the context of both the particular claim and the entire patent because "the claims themselves provide substantial guidance as to the meaning of particular claim terms," and claim terms are normally used consistently throughout the patent. *Phillips*, 415 F.3d at 1313-14.

In that regard, courts are instructed to look to the specification, which is a written description of the invention. "[C]laims 'must be read in view of the specification, of which they are a part.'" *Id*. at 1315 (quoting *Markman*, 52 F.3d at 979). Indeed, the specification is perhaps "the single best guide to the meaning of a claim term" due to its statutory requirements of being in

"full, clear, concise, and exact terms." *Id.* at 1316; *see* 35 U.S.C. § 112. "The specification acts as a dictionary when it expressly" or implicitly defines terms used in the claims. *Markman*, 52 F.3d at 979. Thus, it effectively limits the scope of the claim. *On Demand Mach. Corp. v. Ingram Industries, Inc.*, 442 F.3d 1331, 1340 (Fed. Cir. 2006). Due to its nature, "the specification 'is always highly relevant to the claim construction analysis. Usually it is dispositive." *Id*. (quoting *Vitronics*, 90 F.3d at 1582).

Extrinsic evidence includes all evidence external to the patent and prosecution history, e.g., expert and inventor testimonies, dictionaries, and learned treaties. *Markman*, 52 F.3d at 980. It is considered only where the intrinsic evidence does not provide a sufficient description to resolve ambiguities in the scope of the claim. *See Vitronics*, 90 F.3d at 1583; *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999). However, the Federal Circuit has cautioned that dictionary definitions should not be used to interpret patent claim terms in a manner that is divorced from the context and description of the invention in the specification. *Phillips*, 415 F.3d at 1321. In *Phillips*, the Federal Circuit reasoned that because of the nature of the patent claims, the dictionary definitions, as extrinsic evidence, are usually less reliable than the patent documents themselves in establishing the ordinary meaning of a claim term. *Id*. at 1314; *Toro Co. v. White Consol. Indus.*, 199 F.3d 1295, 1299 (Fed. Cir. 1999). Ultimately, extrinsic evidence cannot be used to vary or contradict claim terms when their meanings are discernible from intrinsic evidence. *C. R. Bird, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004).

Overall, in construing the claims, "[t]he judge's task is not to decide which of the adversaries is correct. Instead, the judge must independently assess the claims, the specification, and if necessary the prosecution history, and relevant extrinsic evidence, and declare the meaning of the claims." *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1556 (Fed. Cir. 1995);

MEMS Technology Berhad v. International Trade Com'n, 447 Fed. App'x 142, 153 (Fed. Cir. 2011) (same).

ii. Disclaimers and Disavowals

"[I]n certain cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Ventana Medical Systems, Inc. v. Biogenex Laboratories, Inc.*, 473 F.3d 1173, 1181 (Fed. Cir. 2006) (quoting *Phillips*, 415 F.3d at 1316) (internal citations omitted). In such cases, the Federal Circuit interprets the claim more narrowly than it otherwise would in order to give effect to the patentee's intent to disavow a broader claim scope. *Ventana*, 473 F.3d at 1181 (citing *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1319 20 (Fed. Cir. 2006); *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1342 44 (Fed. Cir. 2001).

However, pointing solely to "general statements by the [patentee] indicating that the invention is intended to improve upon prior art" will not demonstrate that the patentee intended to "disclaim every feature of every prior art device discussed in the 'BACKGROUND ART' section of the patent." *Ventana*, 473 F.3d at 1181; *see also Thorner v. Sony Computer Entertainment America LLC*, 669 F.3d 1362 (Fed. Cir. 2012) ("Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal.") (quoting *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1335 (Fed. Cir. 2009)).

Moreover, the Federal Circuit has found it "particularly important not to limit claim scope based on statements made during prosecution '[a]bsent a clear disavowal or contrary definition." *Digital Vending Services Intern., LLC v. University of Phoenix, Inc.*, 672 F.3d 1270, 1273 (Fed. Cir. 2012) (citing *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1286 (Fed. Cir. 2011) (quoting *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004)). The

reason for such a stringent rule is "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Digital Vending*, 672 F.3d at 1273 (quoting *Phillips*, 415 F.3d at 1317).

III. Analysis

i. Plaintiffs' Construction

Plaintiffs assert that the plain and ordinary meaning of "roflumilast" is "N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxy benzamide active pharmaceutical ingredient." According to Plaintiffs, "[a] person of ordinary skill in the art would understand that the World Health Organization ("WHO") provides INNs in order to 'identif[y] a pharmaceutical substance or active pharmaceutical ingredient by a unique name that is globally recognized and is public property.'" Pls.' Opening Markman Br. ("Pls.' Opening Br.") 7 (quoting Decl. of Alexa Hansen in Supp. of Pls.' Opening Markman Br. ("Hansen Decl.") Ex. 6, WHO, Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances 1 (1997)). Thus, Plaintiffs argue that because INNs are created specifically to identify pharmaceutical compounds, the term roflumilast, by virtue of the fact that it is an INN, carries the implication that it is an active pharmaceutical ingredient.

Additionally, Plaintiffs argue that the specifications and claims of the Patents-at-Issue use the term roflumilast solely to refer to the active pharmaceutical ingredient in the claimed compositions and methods of treatment. As Plaintiffs highlight,

> The claims of the '206, '064, and '142 patents are devoted to methods of treating COPD in a patient, (e.g., Hansen Decl. Ex. 1, '206 patent, all claims), methods of treating acute or chronic airway disorders in patient (e.g., Hansen Decl. Ex. 2, '064 patent, all claims) and "pharmaceutical compositions," "pharmaceutical dosage forms," "compositions" and "pharmaceutical tablets" (e.g., Hansen Decl. Ex. 3,

> '142 patent, all claims). The claims, therefore, define the pharmaceutical role that roflumilast occupies—that of the active ingredient in pharmaceutical compositions, dosage forms and treatments. Indeed, many claims make this even more explicit, by requiring "a therapeutically effective amount of roflumilast," or a pharmaceutical composition thereof (e.g., Hansen Decl. Ex. 1, '206 patent, claim 1; Hansen Decl. Ex. 2, '064 patent, claim 1; Hansen Decl. Ex. 3, '142 patent, claim 4).

Thus, although nowhere in the Patents-at-Issue is the phrase "active pharmaceutical ingredient" used, Plaintiffs contend that based on context, it can be inferred that the plain and ordinary meaning of roflumilast is the Roflumilast Compound with the additional words, "active pharmaceutical ingredient."

However, contrary to Plaintiffs' assertions, the plain and ordinary meaning of roflumilast is clearly provided in the common specifications of the Patents-at-Issue. In each specification, the term roflumilast is introduced with the following statement: "[t]he present invention relates to a novel, improved process for the preparation of N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxybenzamide (INN: roflumilast)." '206 Patent at 1:14-17; '064 Patent at 1:16-19; '142 Patent at 1:16-19. In this manner, the language of each specification clearly identifies the term roflumilast as shorthand for the Roflumilast Compound, with no mention of its status as a pharmaceutical ingredient. Thus, although latter portions of the specifications and claims of the Patents-at-Issue refer to pharmaceutical uses for roflumilast, this does not narrow the plain and ordinary meaning of roflumilast to an active pharmaceutical ingredient. Rather, the specifications of the Patents-at-Issue make clear that roflumilast is simply shorthand for the Roflumilast Compound alone.

Moreover, Plaintiffs' proposed construction runs counter to "the well-established rule that 'claims are interpreted with an eye toward giving effect to all terms in the claim.'" *Digital Vending*, 672 F.3d at 1275 (quoting *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006)).

Pursuant to this rule, courts "constru[e] claim terms in light of the surrounding claim language, such that words in a claim are not rendered superfluous." *Digital Vending*, 672 F.3d at 1275. "For example, when a claim refers to 'steel baffles,' this strongly implies that the term 'baffles' does not inherently mean objects made of steel." *Id.* (quotations omitted).

In the present case, the '142 Patent recites a roflumilast "composition" in one claim and a roflumilast "pharmaceutical composition" in a different claim. '142 Patent at 8:23-26, 8:33-38. Claim 1 of the '142 Patent recites:

> A **composition** comprising: roflumilast having a purity greater than or equal to 99% by weight and N-(3,5-dichlo-ropyrid-4-yl)-3-cyclopropylmethoxy-4-hydrobenzamide present (relative to roflumilast) in an amount greater than zero and less than 0.1% by weight.

'142 Patent at 8:23-26 (emphasis added). Claim 4 of the '142 Patent recites:

> A **pharmaceutical composition** comprising: roflumilast having a purity greater than or equal to 99% by weight and N-(3,5-dichlo-ropyrid-4-yl)-3-cyclopropylmethoxy-4-hydrobenzamide present (relative to roflumilast) in an amount greater than zero and less than 0.1% by weight; and pharmaceutically acceptable auxiliaries and/or excipients.

Id. at 8:33-38 (emphasis added). Including "active pharmaceutical ingredient" in the definition of roflumilast implies that any composition of which it is an ingredient will be pharmaceutical in nature. Thus, if the Court were to apply Plaintiffs' construction of roflumilast to claim 4 in the '142 Patent, the term pharmaceutical would be rendered superfluous. Furthermore, under Plaintiff's construction, there would apparently be no functional differentiation between claim 1 and claim 4, as they would both be "pharmaceutical compositions."

For these reasons, Plaintiffs' proposed addition of "active pharmaceutical ingredient" to the plain and ordinary meaning of roflumilast has no support in the intrinsic record. Furthermore, because the language of the Patents-at-Issue themselves are sufficient to resolve any ambiguities

in the plain and ordinary meaning of the term roflumilast, the Court will not consider any extrinsic evidence submitted by Plaintiffs. *See Vitronics*, 90 F.3d at 1583; *Johnson Worldwide*, 175 F.3d at 989. Accordingly, the Court finds that the plain and ordinary meaning of "roflumilast" is the Roflumilast Compound – N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxybenzamide.

ii. Torrent Defendants' Construction

Torrent Defendants do not dispute that the plain and ordinary meaning of roflumilast is the Roflumilast Compound. Instead, Torrent Defendants argue that rather than construing roflumilast by its plain and ordinary meaning, roflumilast should be construed within the Patents-at-Issue as the Roflumilast Compound prepared by a certain method – specifically, roflumilast synthesized using a molar ratio of the anion of 4-amino-3,5-dichloropyridine to the activated derivative of 3-cyclopropylmethoxy-4-difluoromethoxybenzoic acid of at least 1.5 and at most 3 (the "AZ Process").[2] Torrent Defendants assert that because "[t]he purported invention of the patents-in-suit is a process for making roflumilast [and] the patents-in-suit disavow roflumilast made by any other process[, therefore] the term 'roflumilast' in the patents-in-suit should be construed as a product of the disclosed process." Torrent Defs.' Opening Claim Construction Br. ("Torrent's Opening Br.") 2.

First, the Court notes that despite the fact that large portions of the specifications of the Patents-at-Issue are dedicated to disclosing processes for the production of roflumilast, the Patents-at-Issue do not claim such processes. Instead, the Patents-at-Issue claim methods for the treatment of airway disorders and claim a chemical composition composed primarily of roflumilast. '206

[2] The parties dispute whether the AZ Process indeed encompasses the entirety of the processes for producing roflumilast disclosed in the Patents-at-Issue.

Patent at 8:21-10:34; '064 Patent at 8:37-10:33; '142 Patent at 8:22-9:21. Indeed, in this family of patents, it is the '791 Patent, not any of the Patents-at-Issue, which claims processes for the production of roflumilast. Moreover, for the reasons set forth below, the Court does not find that the Patents-at-Issue expressly disavow roflumilast made by all processes other than the AZ Process. Consequently, Torrent Defendants have failed to provide a basis for the Court to deviate from the plain and ordinary meaning when construing roflumilast.

"To prevail, [Torrent Defendants] must establish [that] the inventors demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Epistar*, 566 F.3d at 1334 (quotations and brackets omitted). Given the highly limited circumstances where it is permissible to depart from a term's plain and ordinary meaning, the Federal Circuit has cautioned that a court must take care not to import limitations into the claims from the specification. *See Hill-Rom Servs. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) ("While we read claims in view of the Case specification . . . we do not read limitations from the embodiments in the specification into the claims."). Instead, "[d]isavowal requires that the specification or prosecution history make clear that the invention does not include a particular feature, or is clearly limited to a particular form of the invention." *Id.* (quoting *SciMed Life Sys.*, 242 F.3d at 1341 and *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1330 (Fed. Cir. 2009)) (quotations and brackets omitted).

Furthermore, "generally[,] product claims are not limited to the methods of manufacture disclosed in the specification and . . . the method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process. . . . A novel product that meets the criteria of patentability is not limited to the process by which it was made."

Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1375 (Fed. Cir. 2007) (quoting *Vanguard Prods. Corp.*, 234 F.3d at 1372-73) (quotations and brackets omitted). Production process steps should only be treated as part of a product claim "if the patentee has made clear that the process steps are an essential part of the claimed invention." *Andersen*, 474 F.3d at 1375.

Nonetheless, Torrent Defendants argue that statements in the Patents-at-Issue relating to one particular method of making roflumilast are "expressions of manifest exclusion or restriction" that represent "a clear disavowal of claim scope" of composition and method of treatment claims. Torrent's Opening Br. at 22. However, each of the alleged manifest exclusions in the Patents-at-Issue to which Torrent Defendants cite merely describe aspects of the process disclosed in the specification for the production of roflumilast, and do not explicitly exclude all other methods for producing roflumilast. Indeed, insofar as the Patents-at-Issue state that certain other methods of preparing roflumilast or piclamilast (a related compound) are not suitable for the industrial preparation of roflumilast of high purity, they only criticize those specifically identified methods. '206 Patent at 2:15-19, '064 Patent at 2:19-24, '142 Patent at 2:14-18.[3] As such, these disclaimers

[3] The Patents-at-Issue state in pertinent part:

> None of the processes described in the international applications WO 93/25517 and WO 94/02465 for preparing piclamilast, nor the process described in WO 95/01338 for preparing roflumilast, appear to be suitable for the industrial preparation of roflumilast of high purity.
>
> Although the improved process described in Organic Process Research & Development 2, 157-168 (1998) for preparing 3-(cyclopentyloxy)-N-(3,5-dichloropyrid-4-yl)-4-meth-oxybenzamide (INN: piclamilast) has already been optimized for feasibility on the industrial scale, when applied analogously to roflumilast it leads to the formation of more than 3% by weight of the by-product N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-hydroxybenzamide, which cannot be reduced even by multiple recrystallization.

'206 Patent at 2:15-28, '064 Patent at 2:19-33, '142 Patent at 2:14-27.

do not indicate that the patentee intended to disclaim *all* methods other than the AZ Process to produce the highly pure roflumilast needed to create the composition claimed in the '142 Patent or needed to implement the processes claimed in the '206 and '064 Patents. *See also Thorner v. Sony Computer Entertainment America LLC*, 669 F.3d 1362 (Fed. Cir. 2012) ("Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal.")

Moreover, the specification makes clear that the disclosed process for producing roflumilast only "relates to" the invention claimed in the Patents-at Issue. Consequently, these alleged disavowals simply provide further information about the claims without expressly restricting their scope. For example, Torrent Defendants cite to the following portions of the '206 Patent:

> • The invention **relates to** novel processes for the preparation of high-purity roflumilast. '206 Patent at 1:1-2 (emphasis added).
>
> • The **invention furthermore relates to** a method for the treatment of mammals, including humans, suffering from one of the mentioned diseases. The method is characterized in that a therapeutically effective amount of roflumilast prepared by one of the processes described above is administered together with conventional auxiliaries and/or excipients to the mammal with the disease. Preferably the disease is an acute or chronic airway disorder (for example, asthma, bronchitis, allergic rhinitis, emphysema, and COPD) . . . . *Id*. at 5:35-43 (emphasis added).
>
> • The **invention also relates to** the use of roflumilast prepared by one of the processes described above for the production of pharmaceutical compositions which are employed for the treatment and/or prophylaxis of the diseases mentioned. *Id*. at 5:26-29 (emphasis added).

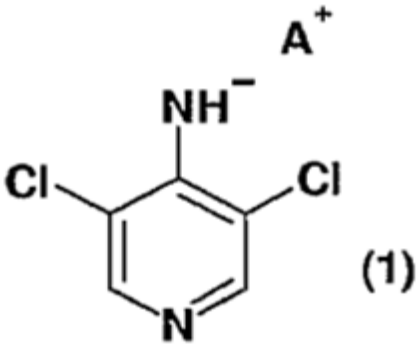
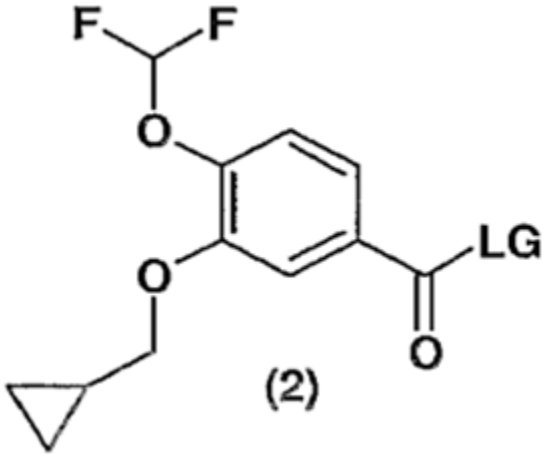
The above statements do not disavow or disclaim other methods of producing roflumilast, because they only "relate to" the inventions claimed in the Patents-at-Issue. In sum, the language of the Patents-at-Issue does not demonstrate "an intent to deviate from the ordinary and accustomed meaning of [roflumilast]." *Epistar*, 566 F.3d at 1334.

Torrent Defendants also argue that the prosecution history of the Patents-at-Issue supports construing roflumilast more narrowly than its plain and ordinary meaning. However, to the contrary, the Court finds that the prosecution history demonstrates that the inventors purposefully chose not to restrict the claims in the Patents-at-Issue to roflumilast produced by the process disclosed in the patents' specifications.

The Patents-at-Issue claim priority to, *inter alia*, a PCT application filed on March 8, 2004. '206 Patent at 1:4-9; '064 Patent at 1:4-13; '142 Patent at 1:4-13. On April 18, 2005, the PCT application became the first U.S. patent application in this family, U.S. Ser. No. 10/531,720 (the "'720 Application"). '206 Patent at 1:4-9; '064 Patent at 1:4-13; '142 Patent at 1:4-13. On December 10, 2008, the first patent issued from the '720 Application, the '791 Patent, which claimed certain processes for the preparation of highly pure roflumilast. '206 Patent at 1:4-9; '064 Patent at 1:4-13; '142 Patent at 1:4-13; '791 Patent at 8:29-20:6. The next application in the priority chain, U.S. Ser. No. 12/292,795 (the "'795 Application") was filed as a continuation of the '791 Patent on November 26, 2008. 206 Patent at 1:4-9; '064 Patent at 1:4-13; '142 Patent at 1:4-13. Ultimately, the '795 Application was abandoned, but not before the applicants filed U.S. Ser. No. 13/547,945 ("the '945 Application") on July 12, 2012. 206 Patent at 1:4-9; '064 Patent at 1:4-13; '142 Patent at 1:4-13. Subsequently, the applicants amended the claims in the '945 Application, to remove language expressly limiting the roflumilast utilized in the claims to roflumilast produced by a particular process. Hansen Decl. Ex. 16, '206 Patent Prosecution History, July 12, 2012 Preliminary Amendment; *see also* Hansen Decl. Ex. 17, '064 Patent Prosecution History, April 10, 2013 Preliminary Amendment; Hansen Decl. Ex. 18, '142 Patent Prosecution History, April 10, 2013 Preliminary Amendment. The '945 Application eventually issued as the '206 patent. '206

Patent at 1:4-9. The applications leading to the '064 and '142 Patents were later both filed as continuations of the '945 Application. '064 Patent at 1:4-13; '142 Patent at 1:4-13.

Prior to amending the '945 Application, all patent applications in this family involved claims which expressly utilized only roflumilast produced by a particular process. For example, claim 1 of the '720 Application claims:

> [p]rocess for the preparation of roflumilast by reacting the anion of 4-amino-3,5-dichloropyridine (1)
>
> 
>
> (1)
>
> in which A+ is a cation, preferable an alkali metal cation and particularly preferably a potassium cation, with an activated derivative of 3-cyclopropylmethoxy-4-difluoromethoxybenzoic acid (2),
>
> 
>
> (2)
>
> in which LG is a suitable leaving group, preferable a chlorine atom, characterized in that the molar ratio of the employed anion of the 4-amino-3,5-dichloropysidine (1) to the activated derivative of 3-cyclopropylmethoxy- 4-difluoromethoxybenzoic acid (2) is at least 1.5 and at most 3.

'720 Application at 11. Similarly, the '791 Patent and '795 Application include product-by-process claims directed to roflumilast made by particular disclosed processes, and process claims for the use of roflumilast prepared by such processes. '791 Patent at 8:29-20:6; '795 Application at 4-5. In contrast, the amended '945 Application and the resultant Patents-at-Issue do not limit their claims to roflumilast produced by certain processes, but instead only refer to roflumilast generally, or roflumilast of a minimum level of purity. *See* Hansen Decl. Ex. 16, '206 Patent Prosecution History, July 12, 2012 Preliminary Amendment; *see also* Hansen Decl. Ex. 17, '064 Patent Prosecution History, April 10, 2013 Preliminary Amendment; Hansen Decl. Ex. 18, '142 Patent Prosecution History, April 10, 2013 Preliminary Amendment.

Torrent Defendants argue that the Court should look to the scope of the claims in the priority patent applications as evidence of the essential features of the invention in the Patents-at-Issue. Put another way, Torrent Defendants argue that express limitations in the claims of priority patent applications should be imported into the claims of subsequently issued patents that were amended to remove those express limitations. In making this argument, Torrent Defendants mistakenly cite to *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998) for this proposition. Torrent's Opening Br. at 36. In *Gentry*, the Federal Circuit determined that certain of the plaintiff patent holder's broader claims for a sectional sofa were invalid, because these claims were directed towards sectional sofas in which the location of the reclining controls were not located on a console, while an essential element of the invention disclosed in the specification was that such controls were located on a console. 134 F.3d at 1480. As further evidence that this was an essential element of the claimed invention, the *Gentry* court cited to the fact that the claims in the original application had only included sofas with controls located on a console. *Id.* As such,

Gentry stands for the proposition that claims which do not include an essential element of the disclosed invention are overbroad, and therefore invalid. *Id.* Contrary to Torrent Defendants' assertions, *Gentry* does not stand for the proposition that, even in the absence of an express disavowal or disclaimer in the patent, courts should construe claim terms to incorporate limitations that were included in prior iterations of a patent application, but have since been removed. Furthermore, unlike the present case, the *Gentry* court found that the express language in the patent itself identified the console as an essential element of the disclosed invention. Moreover, the *Gentry* court did not attempt to re-define the terms in the over-broad claims in that case. Instead, the *Gentry* court simply determined that such claims were invalid. Whether the claims in the Patents-at-Issue are invalid is not a question presently before this Court.

The Federal Circuit has cautioned against construing a claim term more narrowly based on limitations in related patents that are omitted from the patent at issue. *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1333 (Fed. Cir. 2010). In such circumstances, the fact that the applicants included the limiting language in the other patents but omitted it from the patent at issue, demonstrates that the applicants knew how to use such language and "specifically omitted" it from the patent at issue. *See id.* In the present case, the fact that the '791 Patent and the prior applications included the kind of limiting language that Torrent Defendants now seek to include in the construction of roflumilast demonstrates that the applicants knew how to claim roflumilast produced by a certain process and specifically chose not to include such language in the Patents-at-Issue. Accordingly, the Court reads their amendment of the Patents-at-Issue to omit such language as an expression of their intent not to limit their claims to roflumilast produced by any

particular method. As such, the Court finds that the patent prosecution history supports the construction of roflumilast with its plain and ordinary meaning.[4]

In sum, Torrent Defendants have failed to point to a disclaimer or disavowal in the specifications or claims of the Patents-at-Issue that would justify construing roflumilast more narrowly than the plain and ordinary meaning. Additionally, the prosecution history of the Patents-at-Issue demonstrates that the inventors purposefully did not restrict the references to roflumilast in the claims to only roflumilast produced by a certain method. Consequently, Torrent Defendants have failed to provide a basis for the Court to deviate from the plain and ordinary meaning of roflumilast.

IV. Conclusion

For the foregoing reasons, the Court construes "roflumilast" by its plain and ordinary meaning as "N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxybenzamide."

Date: October 18, 2016

/s/ Freda L. Wolfson
Freda L. Wolfson
U.S. District Judge

[4] Torrent Defendants also argue that a declaration filed by one of the named inventors, Walter Palosch ("Palosch Declaration") during the prosecution of the '945 application, demonstrates that the Patents-at-Issue were differentiated from the prior art solely on the basis of the process by which the roflumilast was produced. However, to the contrary, the purpose of the Palosch Declaration was to show that roflumilast did not inherently contain the 4-hydroxy impurity, and that the claimed compositions and methods of using those compositions were themselves novel and non-obvious. *See* Palosch Decl. ¶ 11. Accordingly, the Palosch Declaration is not evidence that the applicants for the Patents-at-Issue attempted to distinguish the claimed inventions from the prior art on the basis of the process by which the roflumilast was produced.